EUROPEAN COMMISSION

Brussels, 5.7.2010
C(2010)4781

COMMISSION DECISION

of 5.7.2010

amending the marketing authorisation for "Thelin - Sitaxentan sodium", a medicinal product for human use, granted by Decision C(2006)3721

(ONLY THE ENGLISH TEXT IS AUTHENTIC)

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(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency[1],

Having regard to Commission Regulation (EC) No 1085/2003 of 3 June 2003 concerning the examination of variations to the terms of a marketing authorisation for medicinal products for human use and veterinary medicinal products falling within the scope of Council Regulation (EEC) No 2309/93[2], and in particular the first subparagraph of Article 6(10) thereof,

Having regard to the application submitted by Encysive (UK) Limited on 20 December 2009 under Article 6(1) of Commission Regulation (EC) No 1085/2003,

Having regard to Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use[3], and in particular Article 61(3) thereof,

Having regard to the opinion(s) of the European Medicines Agency, formulated by the Committee for Medicinal Products for Human Use on 22 April 2010,

Whereas:

(1) An examination of the major variation(s) type II to the terms of the marketing authorisation for the medicinal product "Thelin - Sitaxentan sodium", which is entered in the Community Register of Medicinal Products under number(s) EU/1/06/353/001-005 and the placing on the market of which was authorised by Decision C(2006)3721 of 10 August 2006, has shown that the product remains in compliance with the requirements set out in Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use[4].

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1 OJ L 136, 30.4.2004, p. 1.
2 OJ L 159, 27.6.2003, p. 24.
3 OJ L 311, 28.11.2001, p. 67.
4 OJ L 311, 28.11.2001, p. 67.

(2) The marketing authorisation should be subject to compliance with revised conditions, set out in Annex II to this decision. The implementation of certain of these conditions with regard to the safe and effective use of the medicinal product is to be ensured by the Member States, in accordance with Article 127a of Directive 2001/83/EC. To this effect, Commission Decision (2010)4782 of 5.7.2010 is simultaneously being addressed to the Member States.

(3) It is therefore appropriate to accept the application(s) in respect of (a) major variation(s) to the terms of the marketing authorisation and to amend Decision C(2006)3721 accordingly.

(4) Encysive (UK) Limited submitted, under Article 61(3) of Directive 2001/83/EC, a notification(s) for changes to an aspect of the labelling or the package leaflet, which has (have) not yet been included in Decision C(2006)3721 of 10 August 2006.

(5) The marketing authorisation should be updated, and Decision C(2006)3721 amended accordingly.

(6) For the sake of clarity and transparency, it is advisable, following the amendment of part or parts of the Annexes, to provide for a consolidated version thereof. The Annexes to Decision C(2006)3721 should therefore be replaced,

HAS ADOPTED THIS DECISION:

Article 1

Decision C(2006)3721 is amended as follows:

1) The following list of notifications for changes to an aspect of the labelling or the package leaflet is added to the updated marketing authorisation;

Application number	Annex (EU numbers affected)
EMEA/H/C/679/N/30	IIIB (EU/1/06/353/001-005)

2) Annex I is replaced by the text set out in Annex I to this Decision;

3) Annex II is replaced by the text set out in Annex II to this Decision;

4) Annex III B is replaced by the text set out in Annex III B to this Decision.

Article 2

This Decision is addressed to Encysive (UK) Limited, Alder Castle House, 10 Noble Street, London EC2V 7QJ, United Kingdom.

Done at Brussels, 5.7.2010.

For the Commission
Paola TESTORI COGGI
Director-General